ARC 5007C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to pharmacy practices

The Board of Pharmacy hereby amends Chapter 3, "Pharmacy Technicians," Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 13, "Telepharmacy Practice," and Chapter 21, "Electronic Data and Automated Systems in Pharmacy Practice," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 147.76, 155A.13, 155A.13A, 155A.19 and 155A.33A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 147.76, 155A.13, 155A.13A, 155A.19 and 155A.33A.

Purpose and Summary

These amendments:

- Replace the phrase "tech-check-tech program" with "technician product verification program" throughout the Board's rules,
- Require a nonresident pharmacy applicant to identify a registered location located in Iowa,
- Extend the time frame in which a pharmacy must respond to a request for original records from 48 to 72 hours,
- Amend language relating to requirements for closing a pharmacy which may be exempt in the event of an unforeseeable closure, and
- Simplify the rule relating to the delivery of prescription drugs.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on October 9, 2019, as **ARC 4695C**.

The Board received three comments regarding the rule making. Two comments were received from chain pharmacies (one of which also operates mail order pharmacies) in opposition to the language which would require that patient counseling, when required pursuant to rule 657—6.14(155A), be provided prior to the delivery of a patient's new or changed medication. The Board believes patient safety is best protected when the patient is counseled about the patient's new or changed medication prior to the medication being dispensed so that the patient has the opportunity to decline the medication if the patient wishes.

The third comment was submitted from the Iowa Pharmacy Association, which expressed support of the rule making and included this comment about the patient counseling: "While the revisions to 657—8.15(155A) Delivery of prescription drugs and devices contained in Item 8 do not substantively change the counseling requirements for delivery of prescription drugs, it is imperative the Board maintains strict regulation and enforcement of existing patient counseling requirements in Iowa. This is especially important when prescriptions are delivered, as losing face to face contact with a patient makes it harder to provide vital information, advice, and assistance regarding their medications. Without measured and effective regulation, pharmacist's ability to exercise professional judgment in the provision of patient counseling can be compromised."

Item 13 has been changed from the Notice to account for the amendment made to the Iowa Administrative Code in Item 3 of **ARC 4798C** (IAB 12/4/19). No other changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board on February 26, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on April 29, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend subrule 3.21(1) as follows:

3.21(1) *Technical dispensing functions.* A pharmacist may delegate technical dispensing functions to an appropriately trained and registered pharmacy technician, but only if the pharmacist is on site and available to supervise the pharmacy technician when delegated functions are performed, except as provided in rule 657—6.7(124,155A) or 657—7.6(155A), as appropriate, or as provided for telepharmacy in 657—Chapter 13. Except as provided for an approved ~~tech-check-tech~~ technician product verification program pursuant to 657—Chapter 40, the pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative. A pharmacy technician shall not delegate technical functions to a pharmacy support person.

ITEM 2. Amend rule 657—3.23(155A) as follows:

657—3.23(155A) Tasks a pharmacy technician shall not perform. A pharmacy technician shall not be authorized to perform any of the following judgmental tasks:

1. Except for a certified pharmacy technician participating in an approved ~~tech-check-tech~~ technician product verification program pursuant to 657—Chapter 40, provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

2. to 6. No change.

ITEM 3. Amend rule 657—6.8(124,155A) as follows:

657—6.8(124,155A) Prescription processing documentation. All prescriptions shall be dated and assigned a unique identification number that shall be recorded on the original prescription, except as provided in 657—subrule 21.5(1). The original prescription shall be retained by the pharmacy filling the prescription and shall be maintained in the original format as received by the pharmacy. Dispensing documentation shall include the date of fill or refill; the name, strength, and National Drug Code (NDC) of the actual drug product dispensed; and the initials or other unique identification of the pharmacist, pharmacist-intern, or technician in an approved ~~tech-check-tech~~ technician product verification program. Dispensing documentation shall be maintained and be readily available.

ITEM 4. Amend subrule 6.16(2) as follows:

6.16(2) *Storage of records.* Original hard-copy prescriptions and other pharmacy records shall be maintained by the pharmacy for a minimum of two years from the date of the record in accordance with this subrule.

a. Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within ~~48~~ 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

b. Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within ~~48~~ 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

ITEM 5. Amend paragraph **7.6(1)"b"** as follows:

b. Certified pharmacy technicians. Pursuant to the pharmacy's policies and procedures, a certified pharmacy technician may be granted access to the pharmacy department to perform authorized technical functions. In the absence of a pharmacist, a certified pharmacy technician may only dispense, deliver, or distribute a drug, including a compounded preparation and controlled substance, when the drug is verified by a pharmacist, including by a remote pharmacist, except as authorized in an approved ~~tech-check-tech~~ technician product verification program. A certified pharmacy technician may assist a licensed health care professional in locating a drug to meet the emergent needs of a patient but shall not provide final verification of the accuracy of the drug product obtained.

ITEM 6. Amend subrule 7.13(4) as follows:

7.13(4) *Storage of records.* Original hard-copy records shall be maintained by the pharmacy for a minimum of two years from the date of the record in accordance with this subrule.

a. Records shall be maintained within the pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the pharmacy department, including at a remote location, if the pharmacy has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within ~~48~~ 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

b. Records more than 12 months old may be maintained in a secure storage area outside the pharmacy department, including at a remote location, if the records are retrievable within ~~48~~ 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

ITEM 7. Amend rule 657—8.9(124,155A) as follows:

657—8.9(124,155A) Records storage. Every record required to be maintained by a pharmacy pursuant to board rules or Iowa Code chapters 124 and 155A shall be maintained and be available for inspection and copying by the board or its representative for at least two years from the date of such record or the date of last activity on the record unless a longer retention period is specified for the particular record.

8.9(1) *Records less than 12 months old.* Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy has retained electronic copies of the records in the pharmacy that are immediately available and if the original records are available within ~~48~~ 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

8.9(2) *Records more than 12 months old.* Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within ~~48~~ 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

ITEM 8. Rescind rule 657—8.15(155A) and adopt the following **new** rule in lieu thereof:

657—8.15(155A) Delivery of prescription drugs and devices. A prescription order may be delivered to a patient at any location licensed as a pharmacy. Alternatively, a pharmacy may use the mail, a common carrier, or personal delivery to deliver a prescription order to any location requested by the patient. A pharmacy that delivers prescription orders by one or more alternate methods shall have policies and procedures to ensure patient confidentiality, prescription order accountability, and proper storage of prescription orders during delivery. When counseling is required pursuant to rule 657—6.14(155A), oral counseling shall be provided before the prescription order is delivered to the patient. Documentation of the delivery of prescription orders shall be maintained by the pharmacy for at least two years from the date of delivery. The term "patient" includes the patient and the patient's authorized representatives.

ITEM 9. Amend rule 657—8.24(155A) as follows:

657—8.24(155A) Documented verification. The pharmacist shall provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative. In an approved ~~tech-check-tech~~ technician product verification program, the checking technician shall provide, document, and retain a record of the final verification for the accuracy of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

ITEM 10. Amend paragraphs **8.35(2)"d"** and **"e"** as follows:

d. Criminal and disciplinary history information; ~~and~~

e. Description of the scope of services provided by the pharmacy~~.~~; and

ITEM 11. Adopt the following **new** paragraph **8.35(2)"f"**:

f. If the pharmacy is located outside of Iowa, identification of a registered agent located in Iowa.

ITEM 12. Amend subrule 8.35(7) as follows:

8.35(7) *Closing or sale of a pharmacy.* A closing pharmacy shall ensure that all pharmacy records are transferred to another licensed pharmacy that agrees to act as custodian of the records for at least two years. A pharmacy shall not execute a sale or closing of a pharmacy unless there exists an adequate period of time prior to the pharmacy's closing for delivery of the notifications to the pharmacist in charge, the board, the DEA, and pharmacy patients as required by this subrule. ~~However, the provisions of this subrule regarding prior notifications to the board, the DEA, and patients shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster.~~ The executive director may exempt a pharmacy from one or more of the notification requirements in the event of an unforeseeable closure.

a. to *h.* No change.

ITEM 13. Amend subrule 13.8(7) as follows:

13.8(7) *Prohibited activities.* In the physical absence of a pharmacist, the following activities are prohibited:

a. to *c.* No change.

d. Technician product verification program activities.

e. and *f.* No change.

ITEM 14. Amend rule **657—21.2(124,155A)**, definitions of "Pharmacist verification" and "Readily retrievable," as follows:

"Pharmacist verification" or *"verified by a pharmacist"* means the accuracy of a prescription drug is verified by a pharmacist, pharmacist-intern, or technician in an approved ~~tech-check-tech~~ technician product verification program.

"Readily retrievable" means that hard-copy or electronic records can be separated out from all other records within ~~48~~ 72 hours of a request from the board or other authorized agent.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 3/25/20.